DUR Board Meeting Minutes Final

Name of Meeting	Drug Utilization Review Board
Date of Meeting	Thursday, August 28, 2008
Length of Meeting	2:12 PM – 3:08 PM
Location of Meeting	DMAS Board Room 13th Floor

Members Present:
Geneva Briggs, PharmD
Avtar Dhillon, MD
Jason Lyman, MD, MS
Sandra Dawson, R.Ph, MSHA
Jane Settle, NP
Randy Ferrance, MD
Renita Driver, PharmD

(Not Present: James Evans, MD, Michele Thomas, PharmD, Jamie Haight, R.Ph, Bill Rock, PharmD, Jonathan Evans, MD)

DMAS Attendees:
Bryan Tomlinson, Health Care Services Division Director
Phillip Amiss, Pharmacy Program Manager
Rachel Cain, PharmD
Keith Hayashi, R.Ph
Tyrone Wall, Compliance Specialist
Meredith Lee, Health Care Services Policy Analyst

Contractor: Donna Johnson, R.Ph, First Health Services Corporation
Debbie Moody, R.Ph, First Health Services Corporation

Guest
Paula Pitman, TAP
Brandon Morris, Lilly
Matt Benedetti, Astra Zeneca
Cal Whitehead, Wyeth
Rob Berringer, ACS
Brad Lanham, BMS
RJ Gilson, ACS
Richards Grossman, Vectre
Bobbi Simmers, Johnson & Johnson
Doug Shilling, Cephalon
Matt Sheffield, BIPI

Call to Order and Introductions

Chair Geneva Briggs called the meeting to order and asked everyone to introduce themselves.

Geneva introduced Phillip Amiss the new Pharmacy Program Manager.

The Board reviewed and with a motion, approved the minutes from April 24, 2008.

Behavioral Health Pharmacy Program

Janie Shivar of Comprehensive NeuroScience (CNS) joined via conference call to update the Board on the Behavioral Health Program. The Board agreed the Noradrenergic agonists Drug Class data should be sent to CNS so that we may capture the utilization within the Va. Medicaid population. Also, once the Physician specialty codes are received by CNS, ad hoc reports may be run to determine if the appropriate physicians are prescribing these behavioral medications.

New Drugs

Ms. Johnson presented criteria for the new drugs: Ciclesonide, Olopatadine, and Desvenlafaxine. The Board approved the criteria with the following recommendations:

Ciclesonide criteria were approved with a motion by the Board
Olopatadine criteria were approved with a motion by the Board
Desvenlafaxine criteria were approved with a motion by the Board

Potential Review Topics

The evaluation of medication adherence using Medication Possession Ratio (MPR) and high dose Methadone utilization were discussed as Potential topics for RetroDUR Reviews.

ProDur Reports

The review of ProDUR reports included a Summary of ProDUR Alerts, ProDUR Cost Savings Report, Cost and Utilization Analysis by Drug Type, Top 25 Drugs Ranked by Payment Amount, and Top 25 Drugs Ranked by Claim Count.

RetroDur Reports

RetroDUR reports for March, May, and June included FDA Alert – Biphosphonates, Beers Criteria Review, Diabetic Care in Mental Illness Patients, and Iron Supplementation in Epoetin Therapy. The RetroDUR process for April was a Polypharmacy review.

March 2008 - FDA Alert - Bisphosphonates

The Retrospective Drug Utilization Review process for March 2008 reviewed drug claims for February 2008. This month's topic of review was the FDA warning regarding the risk of severe musculoskeletal pain associated with bisphosphonates.

In January 2008, the FDA issued a warning about the possibility of severe and sometimes incapacitating bone, muscle and/or joint pain in patients taking bisphosphonates. The studies show that there is no definite time frame for when these adverse effects may occur. It may be days, months or years after starting the therapy. The risk factors and incidence of the associated with pain are still unknown.[1]

Patient profiles were reviewed for current claims for a bisphosphonate. A total of 257 letters were sent to prescribers informing them of the potential risks to their patients based on the FDA alert. Prescribers will need to monitor their patients for symptoms of musculoskeletal pain and determine if their bisphosphonate may be responsible. It may be necessary to temporarily or permanently discontinue the bisphosphonate therapy.

There were also re-reviews this month for the July 2007 review for the FDA warning regarding the potential safety issue related to Avandia (rosiglitazone) and the increased risk of heart attack and other heart-related deaths.[2] For the original review, 306 letters were sent to prescribers to alert them to the potential risks to their patients as stated in the FDA Alert. Of these original patients, 155 showed no change in therapy while 151 discontinued their previous therapies.

April 2008 – Polypharmacy

The Retrospective Drug Utilization Review process for April 2008 reviewed drug claims for March 2008. This month's topic of review was polypharmacy.

Patients who are seen by multiple prescribers and have their prescriptions filled at multiple pharmacies are at increased risk of medication related adverse events. These patients may lack a primary care physician and a single pharmacy to coordinate and optimize their medication regimen. The focus of this review was to evaluate patients who received greater than nine unique prescriptions in a 34-day period and these prescriptions were written by 3 or more different prescribers and filled at 3 or more different pharmacies. The profiles of patients meeting these criteria were reviewed. Care was taken not to letter when the patients had obvious diseases or combination of diseases that would easily require more than nine prescriptions each month and possibly several doctors. Staff looked for patients who are chronically at risk for drug interactions, therapeutic duplication, or those who may be doctor or pharmacy shopping. A total of 42 letters were sent to prescribers informing them of their patients' polypharmacy and the potential risks.

Since the polypharmacy review was incorporated into the existing RetroDUR program in August 2005, approximately 9000 patient medication profiles have been reviewed and a total of 1032 (11%) intervention letters have been sent to prescribers. The overall prescriber response rate through the November 2007 review remains at 22% with 59% of these prescribers responding that they find the information useful and plan to monitor alter or discontinue the treatment regimen.

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[1] FDA Alert [1/7/2008] http://www.fda.gov/cder/drug/infopage/bisphosphonates/default.htm.

[2] FDA Issues Safety Alert on Avandia. FDA News. Available at http://www.fda.gov/bbs/topics/NEWS/2007/NEW01636.html

There were also re-reviews this month for the September 2007 review of new drug and therapeutic class criteria. Profiles for patients with DUR criteria violations for Growth Hormones, Hepatitis C Agents, Low Molecular Weight Heparins and Antiretroviral Agents were reviewed. Staff looked for drug interactions, therapeutic duplication, high doses, and drug to disease interactions. In addition to these problem types, staff also looked for non-compliance with the antiretroviral agents. A total of 22 letters were sent to prescribers informing them of the potential risk to their patients. Of these original patients, only 10 show no change in therapy.

May 2008 - Beers Criteria Review

The Retrospective Drug Utilization Review process for May 2008 reviewed drug claims for April 2008.

The 2003 session of the Virginia General Assembly passed legislation requiring the Department of Medical Assistance Services to review its elderly long-term care enrollees for any inappropriate use of medications as defined by Dr. Mark Beers. [3] Dr. Beers has published several articles describing the inappropriate use of various medications in older adults. The Beers criteria were presented to the VA Medicaid DUR Board for review and approval. The Board approved the criteria and agreed that this review would be performed every 6 months as a retrospective review of 1000 enrollee medication profiles. Additionally, the Board recommended that the review should include all VA Medicaid enrollees 65 years and older, not just those in long-term care facilities.

With the implementation of the Medicare part D pharmacy drug plan, Medicaid no longer covers the majority of the medications on the Beers List. However, two major classes of drug are excluded by Medicare and are covered by Medicaid. These are the benzodiazepines and barbiturates. Additionally, Medicare Part D does not cover over-the-counter (OTC) medications. OTC medications such as antihistamines and decongestants are included in the Beers criteria. Therefore, the focus of this review is on the Beers criteria for these types of medications. One thousand medication profiles were generated for all enrollees 65 years and older who met any of the Beers criteria for benzodiazepines, barbiturates or OTCs. During the review, staff noticed there were some older adults who were not enrolled in Medicare Part D and who were taking inappropriate medications other than those listed above; such as amiodarone, belladonna alkaloids and fluoxetine. These recipients were included in the intervention process.

There were a total of 125 letters sent to prescribers whose patients are receiving medications or dosages that are potentially inappropriate for them. If a prescriber responded to a previous letter that the treatment was clinically appropriate, no letter was sent for this review. Staff must assume that the prescriber has evaluated the risks versus the benefits of using one of these medications in their older patient.

[3] Fick DM, Cooper JW, et al. Updating the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *Arch Intern Med.* 2003;163:2716-2724.

Of particular interest in this review was that 39% of the criteria interventions involved the use of benzodiazepines in doses that exceed the recommended maximum dose in older adults; 46% involved the use of benzodiazepines or barbiturates that are inappropriate to use in older adults at any dosage; 6% of the interventions involved the use of benzodiazepines that are not recommended in patients with certain medical conditions and 9% involved the inappropriate use of the over-the-counter antihistamine, diphenhydramine, as a sedative-hypnotic. Overall, the inappropriate use of these medications can lead to prolonged sedation and an increased incidence of falls and fractures in the older adult patient.

There were also re-reviews this month for the July 2007 review of polypharmacy. For the original review, letters were sent to prescribers concerning 29 patients alerting them of their patient's polypharmacy. Of these original patients, only 5 continue to continue to show polypharmacy.

June 2008 - Diabetic Care in Mental Illness Patients and Iron Supplementation in Epoetin Therapy

The Retrospective Drug Utilization Review process for June 2008 reviewed drug claims for May 2008.

This month staff covered two separate topics – (1) diabetic monitoring in patients with diabetes and a severe mental illness and (2) the lack of iron evaluation testing or supplementation in patients taking epoetin.

Persons with schizophrenia or a major mood disorder have a particularly high incidence of diabetes compared with the general population but they are not always properly monitored. These patients often have certain risk factors and behaviors that can affect long-term diabetes outcomes, such as sedentary lifestyle, obesity, poor diet, smoking and second generation antipsychotic therapy. Diabetic care, including glucose monitoring (HbA1c), retinal eye exams, foot exams, urine protein testing, blood pressure monitoring and lipid assessment, is very important in these patients.[4] For review staff looked to see if any of these tests or procedures was being performed on patients. However, since profiles have a limited time frame of information, staff did not expect to see all of these tests during the review period. Staff main goal was to make sure that some attempt is being made to monitor their diabetes-related health issues. Staff identified 771 patients with both a severe mental illness and diabetes. Overall, the patients reviewed showed good evidence that they are receiving the proper diabetic care and treatment. A total of 28 letters were sent to prescribers when no evidence of any of these monitoring parameters or treatment was seen on their patients' profiles.

Adequate iron stores are necessary for erythropoiesis. During epoetin therapy iron deficiency may develop. Iron deficiency is the most common cause of a suboptimal response to epoetin. Most patients will eventually require iron supplementation to maintain erythropoiesis. Even those patients receiving oral iron supplements need to be monitored as

[4] American Diabetes Association: Standards of Medical Care in Diabetes (Position Statement). *Diabetes Care* 28: (Supplement 1): S4-S35, 2005

the oral route may become ineffective and intravenous iron may be required to replace the iron stores. The manufacturers of epoetin and the National Kidney Foundation KDOQI guidelines recommend evaluation of serum ferritin and transferrin saturation (TSAT) prior to and during therapy with epoetin. [5,6,7] Staff reviewed the profiles of 252 patients receiving epoetin. Staff looked for use of iron supplementation and serum iron level evaluation. The majority of the patients were on an iron supplement and receiving either iron level evaluation or regular hemoglobin/hematocrit testing. Letters were sent to prescribers when there was no evidence of supplementation or evaluation. Since these evaluations are recommended on a periodic basis, patients may indeed have been monitored but just not in the review period. The intent of the letters was simply to alert the prescribers to the possibility that their patients may need closer evaluation. A total of 44 letters were to prescribers to remind them to evaluate their patients if they had not already done so.

There were also re-reviews this month for the September 2007 review of DUR criteria violations for Growth Hormones, Hepatitis C Agents, Low Molecular Weight Heparins and Antiretroviral Agents. Staff looked for drug interactions, therapeutic duplication, high doses, and drug to disease interactions. In addition to these problem types, staff also looked for non-compliance with the antiretroviral agents. A total of 22 letters were sent to prescribers informing them of the potential risk to their patients. Of these original interventions, 1 drug to disease interaction, 5 drug to drug interactions and 4 non-compliance issues still exist.

[1] American Diabetes Association: Standards of Medical Care in Diabetes (Position Statement). *Diabetes Care* 28: (Supplement 1): S4-S35, 2005

Other Business

Dr. Cain updated the Board members on the Medicaid Memorandum which will be mailed in September 2008 regarding the Tamper Resistant Prescription Pad changes effective October 1, 2008.

Next Meetings: Several dates were discussed for future meetings, however the committee decided it would be best to have several dates sent to all members via email in order to compare to their schedules.

Adjournment: 3:08 P.M.

[5] www.kidney.org/professionals/kdoqi/guidelines_updates/doqiupan_iii.html
[6] www.epogen.com